

Exhibit F

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 - - -

5 IN RE: ETHICON, INC. : Master File
6 PELVIC REPAIR SYSTEM : No.
7 PRODUCTS LIABILITY : 2:12-MD-02327
8 LITIGATION :
9 : MDL NO. 2327
10 :
11 MARY K. BURNETT : JOSEPH R. GOODWIN
12 : U.S. DISTRICT JUDGE
13 v. :
14 :
15 ETHICON, INC., et al. : CASE NO.
16 : 2:12-cv-01795
17 - - -

18 July 21, 2016
19 - - -

20
21 Expert deposition of BRIAN
22 J. FLYNN, M.D., taken pursuant to notice,
23 was held at Butler Snow LLP, 500 Office
24 Center Drive, Suite 400, Fort Washington,
Pennsylvania, beginning at 9:36 a.m., on
the above date, before Kimberly A.
Cahill, a Federally Approved Registered
Merit Reporter and Notary Public.

25 - - -
26
27 GOLKOW TECHNOLOGIES, INC.
28 877.370.3377 ph| 917.591.5672
29 deps@golkow.com
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13

& Johnson and Ethicon

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Brian J. Flynn, M.D.

1 - - -
 2 I N D E X
 3 - - -

4
 5 Testimony of: BRIAN J. FLYNN, M.D.
 6 By Mr. McConnell 5
 By Mr. Snell 71
 7 By Mr. McConnell 85
 8

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 10 E X H I B I T S
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12	NO.	DESCRIPTION	PAGE
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14	Flynn- Burnett-1	"Dr. Flynn's Case-Specific Plaintiff Mary Burnett" Black Binder Containing Reports, Records, and "Flynn, July 14th, 2016 Deposition, Burnett Materials" USB	10
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19	Flynn- Burnett-2	Curriculum Vitae of Brian J. Flynn, M.D. Updated 6/28/16	11
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DEPOSITION SUPPORT INDEX

Direction to Witness Not to Answer

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Stipulations

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Question Marked

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Brian J. Flynn, M.D.

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BRIAN J. FLYNN, M.D., after

3

having been duly sworn, was

4

examined and testified as follows:

5

- - -

6

EXAMINATION

7

- - -

8

BY MR. McCONNELL:

9

Q. Good morning, Dr. Flynn. My

10

name is Bob McConnell. I'm one of the

11

lawyers for the Motley Rice law firm and

12

we represent Mary Burnett. I'm here to

13

take your deposition today.

14

We're on the phone -- I'm

15

not going to go through a list of

16

instructions, but we're on the phone, so

17

we should just be cognizant of waiting

18

for me to finish my question and I'll try

19

to wait for you to finish your answer,

20

and I think we can get through this

21

fairly easily.

22

Could you state your name

23

and your occupation for the record,

24

please?

Brian J. Flynn, M.D.

1 A. Yes. I'm Dr. Brian J.
2 Flynn. My occupation is, I'm a urologist
3 and specialist in female pelvic medicine
4 and reconstructive surgery. I'm a
5 professor of surgery and urology at the
6 University of Colorado in Aurora,
7 Colorado.

8 Q. And what's your business
9 address?

10 A. My business address is 1635
11 North Aurora Court, Aurora, Colorado
12 80045.

13 Q. And on the Mary K. Burnett
14 case, when were you first contacted to do
15 work on this case?

16 A. Sometime in maybe January or
17 February of this year.

18 Q. Okay.
19 And what were you asked to
20 do?

21 A. I was asked to serve as an
22 expert witness on the behalf of Ethicon
23 in this case.

24 Q. And what specifically did

1 that entail or what did you then go about
2 to do?

3 A. They asked me to prepare an
4 expert report and to perform an IME on
5 Mrs. Burnett, so in order to do that,
6 that included review of the medical
7 records, preparation of a report,
8 physically performing the independent
9 medical evaluation.

10 I had already completed a
11 general report on TVT Secur, so that was
12 submitted, but that had been prepared
13 previously.

14 Q. Now, you looked at Mrs.
15 Burnett's medical records, I take it.
16 What else did you review, if anything,
17 document-wise?

18 A. Yes. I reviewed expert
19 depositions of the physicians that are on
20 the plaintiff's team, Dr. Jerry Blaivas'
21 expert deposition. I also looked at all
22 the pertinent medical records, looked at
23 some company documents, including the
24 IFU, patient brochures. That's primarily

1 what I did.

2 Q. Did you look at any
3 depositions of treating physicians, Mrs.
4 Burnett's treating physicians?

5 A. I did. I looked at the
6 expert deposition of Dr. Gerald Shirk;
7 Dr. Ann Metzger; and also of one other
8 treater, Dr. Mindrup.

9 Q. Okay.
10 And did you also look at
11 Mrs. Burnett's deposition?

12 A. I believe I did look at that
13 deposition. I don't remember that as
14 well, but I'm fairly certain I did look
15 at that.

16 Q. And what documents have you
17 brought with you to the deposition? Can
18 you describe those for the record,
19 please?

20 A. So I have a large binder,
21 black binder, labeled "Dr. Flynn's
22 Case-Specific Plaintiff Mary Burnett."
23 And this is, you know, a medium-size
24 binder with at least 30 tabs in it.

1 In the binder, that would
2 include my case-specific report, my IME
3 report, some pertinent medical records,
4 and then my reliance list.

5 In the front envelope in
6 that binder, there is a USB that's blue
7 and it has a tag on it. It says "Flynn,
8 July 14th, 2016 Deposition, Burnett
9 Materials."

10 Q. Okay.

11 A. So that -- that's one item.
12 Would you like me to continue?

13 Q. Well, you know, why don't we
14 -- for the record, I'd like to have that
15 marked as Exhibit 1 in its entirety. And
16 I'm going to ask you about the -- your
17 expert opinions and also the examination
18 you did, so just so you know, those will
19 be the two documents specifically I'm
20 going to inquire on.

21 But I'd like to have that
22 binder that you just described marked as
23 Exhibit 1, including the USB device. And
24 that's it for that binder, Doctor.

1

- - -

2

(Deposition Exhibit No.

3

Flynn-Burnett-1, "Dr. Flynn's

4

Case-Specific Plaintiff Mary

5

Burnett" Black Binder Containing

6

Reports, Records, and "Flynn, July

7

14th, 2016 Deposition, Burnett

8

Materials" USB, was marked for

9

identification.)

10

- - -

11

MR. McCONNELL: What else

12

did you bring?

13

THE WITNESS: I have an

14

updated C.V. that was updated on

15

June 28th, 2016.

16

MR. McCONNELL: Okay.

17

THE WITNESS: I have an

18

invoice that had been prepared and

19

submitted in June of this year.

20

And I also have the AUGS

21

position statement in regards to

22

mid-urethral mesh slings for

23

stress urinary incontinence.

24

BY MR. McCONNELL:

1 Q. Anything else?

2 A. That is it.

3 I have given a number of
4 depositions similar to this, so I
5 previously have submitted a list of
6 deposition and trial history. I've
7 submitted a fee schedule in the past.
8 I've submitted e-mails in regards to
9 communications I've had with Ethicon in
10 these cases, so I didn't bring those
11 items, as I've submitted them in with
12 wave 1 depositions.

13 MR. McCONNELL: For the
14 record, why don't we mark the
15 updated exhibit -- I'm sorry --
16 updated C.V. as Exhibit 2.

17 - - -

18 (Deposition Exhibit No.
19 Flynn-Burnett-2, Curriculum Vitae
20 of Brian J. Flynn, M.D. Updated
21 6/28/16, was marked for
22 identification.)

23 - - -

24 BY MR. McCONNELL:

1 Q. Doctor, I just can't read my
2 note. For Exhibit 3, what was the next
3 thing you said after the C.V.?

4 A. Invoice.

5 MR. McCONNELL: Okay. We'll
6 do, the invoice will be 3. And
7 the AUGS document will be 4.

8 - - -

9 (Deposition Exhibit No.
10 Flynn-Burnett-3, 6/16 Invoice, was
11 marked for identification.)

12 - - -

13 (Deposition Exhibit No.
14 Flynn-Burnett-4, AUGS Position
15 Statement, was marked for
16 identification.)

17 - - -

18 BY MR. McCONNELL:

19 Q. Doctor, I don't have the
20 invoice in front of me. How many hours
21 have you spent on this -- on the Burnett
22 case?

23 A. Let's see. I've spent 18
24 hours.

1 Q. And what is your hourly
2 charge?

3 A. It depends on the activity,
4 but it would range from \$400 for record
5 review, \$500 for preparation of the
6 report, IME at \$550 an hour.

7 Q. Okay. And how about
8 deposition time?

9 A. That's not included in this
10 report, but the hourly rate for that is
11 \$600.

12 Q. And I'm sorry. Did you say
13 you've spent to date 18 hours?

14 A. 18 hours up until May 31st.

15 Q. And since May 31st, which
16 was a month and a half ago, can you
17 ballpark how much time, if any, you've
18 spent on this case?

19 A. Yes. I've spent
20 approximately ten hours since then.

21 Q. And what have you done in
22 those ten hours?

23 A. I've reviewed depositions,
24 the ones I mentioned earlier, from Dr.

1 Blaivas and others as they've come in,
2 and I have reviewed the medical records
3 once again, reviewed my report and my
4 IME. I have met with Mr. Snell.

5 This deposition was going to
6 occur, I believe, last Thursday and so I
7 had prepared for that, but -- so those
8 were the activities.

9 Q. You wrote out a formal
10 report and a formal IME. Have you
11 written any other document as it pertains
12 to the Burnett case, including
13 handwritten notes or anything of that
14 nature?

15 A. I had handwritten notes for
16 the IME on Mrs. Burnett. I didn't bring
17 them. I'm not in my home office. I'm in
18 Philadelphia, as you know.

19 So I do have those. I could
20 submit them at another date, but I didn't
21 bring that today.

22 MR. McCONNELL: Okay. I
23 think we -- I think for
24 completeness sake, we'd request

1 that you do submit those to
2 counsel and they'll provide them
3 to us, I'm sure.

4 BY MR. McCONNELL:

5 Q. Any other handwritten or --
6 any other writings that you've done on
7 this case that you haven't described or
8 aren't contained in Exhibit 1?

9 A. No.

10 Q. Doctor, can you turn to your
11 -- the document entitled "Independent
12 Medical Exam of Mary Burnett" with date
13 May 18, 2016, which I assume is included
14 in Exhibit 1?

15 A. Yes.

16 Q. Do you have that in front of
17 you?

18 A. I do.

19 Q. Okay. I'm going to have a
20 series of questions about that. The
21 first question I had was, the location is
22 office of Dr. Steven Geraghty. Is that
23 your business address as well?

24 A. No, that's Dr. Geraghty's

1 business address.

2 Q. Why did you perform your
3 exam of Mrs. Burnett at Dr. Geraghty's
4 office?

5 A. Bowman and Brooke had
6 arranged for me to perform the IME there.
7 I don't have the exact question --
8 answer, but that's where I've done all
9 the IMEs that I've performed in this
10 litigation.

11 Q. Is your office not capable
12 of holding an IME exam?

13 A. No, they're not capable.

14 Q. Why is that?

15 A. It's not part of the
16 ordinary practice, so it's very difficult
17 to schedule there and to accomplish an
18 IME there.

19 Q. Who is Dr. Steven Geraghty?

20 A. I don't know him personally.
21 He's a family physician, family
22 practitioner, in Centennial, Colorado.

23 Q. Now, did you interview Mrs.
24 Burnett as part of your medical exam?

1 A. I did. That was the
2 majority of time spent with her, was
3 during the face-to-face encounter.

4 Q. And approximately how long
5 was that interview?

6 A. Well, the entire IME was one
7 hour, of which the interview part of that
8 was 80 percent of the time, so 50
9 minutes.

10 Q. Okay.
11 Did you take any -- are
12 those the notes you referred to, the
13 handwritten notes?

14 A. That's correct.

15 Q. So you have handwritten
16 notes from that interview?

17 A. Yes. What I do is, with any
18 of the patients I see in my practice or
19 in the IME, I have a template, you know,
20 that has the key areas of the history and
21 physical, and then I fill in the blanks
22 with my handwritten notes and then after
23 that prepare the electronic note.

24 Q. Was anyone else with you and

1 Mrs. Burnett while you interviewed her?

2 A. Yes, there was a medical
3 assistant from Dr. Geraghty's office.

4 Q. And what was her role during
5 the face-to-face interview?

6 A. She was there at the request
7 of the plaintiff. Ordinarily, the
8 medical assistant would be there just for
9 the physical examination, but there was a
10 request made for her to be there for the
11 entire IME, so we honored that request.

12 Q. And who specifically made
13 that request?

14 A. I believe it came from Mrs.
15 Burnett's attorneys.

16 Q. Now, as part of your
17 discussion or interview of Mrs. Burnett,
18 did she discuss any concerns she had
19 about further surgery with you?

20 A. Yeah, we discussed the
21 surgeries that she had and what her
22 future prognosis or surgery -- you know,
23 what sort of things she would need to
24 have done.

1 Q. Did she say that she was
2 concerned or anxious or worried at all
3 about further surgery?

4 A. Yes.

5 Q. And what did you -- did you
6 have a reply to her about that or did you
7 have a discussion with her about that?

8 A. I did.

9 Q. And what did you say?

10 A. I said that it wasn't part
11 of the IME for me to share with her my
12 opinions and prognosis and make
13 recommendations to her, so I informed her
14 that I wasn't going to discuss that with
15 her.

16 Q. Did she bring that up to you
17 or did -- how did that topic even get
18 raised then?

19 A. At the very end of the
20 encounter, similar to what would happen,
21 you know, in my everyday practice, she
22 asked what was wrong with her and what
23 needed to be done in order to address her
24 concerns.

1 Q. Did she discuss any concern
2 that she had about mesh potentially
3 causing damage to a partner in a sexual
4 way?

5 A. We discussed her sexual
6 habits and her love life. I don't
7 remember her specifically asking me if
8 there would be concerns about her
9 partner.

10 Q. Well, what I asked was, did
11 she say she had concerns that the mesh
12 could do some damage to her partner in a
13 sexual encounter.

14 A. I don't recall her asking me
15 that question.

16 Q. And what do you recall about
17 your discussion of her sexual habits and
18 love life?

19 A. She mentioned to me that she
20 was married three times; that she was
21 currently widowed; that her most recent
22 husband had died of bladder cancer and he
23 had his bladder removed. He had a
24 urostomy. And after that surgery, he was

1 unable to perform sex. He was impotent.

2 And she had not had a sexual
3 encounter since 1993, and she is not
4 dating anybody currently since the death
5 of her third husband.

6 Q. How old is Mrs. Burnett?

7 A. Mrs. Burnett at the time I
8 met her was 65 years of age. It looks
9 like she had a birthday [REDACTED] after
10 I had met her, so she's 66, I believe, at
11 the time -- currently.

12 Q. Can you turn to page 4,
13 Doctor, of your medical report or medical
14 exam?

15 A. (Witness complies.) Yes.

16 Q. And in that, you list
17 various categories of examination that
18 you did under "Genitourinary"? It's at
19 the top of the page.

20 A. Yes.

21 Q. What is estrogenization?
22 Where you say severe atrophy, what is
23 estrogenization?

24 A. That's a comment that I make

1 when examining the effects of estrogen on
2 the genitalia and on the vagina.

3 So, you know,
4 estrogenization would imply that there's
5 estrogen in the tissue, making the tissue
6 soft and supple, versus atrophic or dry
7 on the opposite end, and then there's
8 some patients that are in between.

9 So it's a comment reflecting
10 the -- my visualization of the effects on
11 estrogen on the female genitalia.

12 Q. And severe atrophy, I'm
13 sorry, means what?

14 A. Well, atrophy means a
15 shrinking of the tissue, and severe would
16 mean that -- you know, I would say mild,
17 moderate, and severe are the categories
18 that I would use, so that's a reflection
19 of genitalia that has not seen the
20 effects of estrogen in a very long time.

21 Q. And further down, under
22 "Vagina," you make some findings. There
23 was blue mesh exposed that -- and various
24 findings. There's a paragraph of

1 findings there.

2 And I guess my general
3 question is, can you describe how you
4 performed this examination and how did
5 you go about seeing things? Did you
6 physically measure things?

7 Just basically describe the
8 process you took on this examination,
9 please.

10 MR. SNELL: Object; form.

11 Go ahead.

12 THE WITNESS: So after I
13 performed the history, then we
14 went into the physical exam
15 portion. Specific to the
16 genitourinary exam portion of the
17 procedure, the patient is in a
18 lithotomy position, meaning she's
19 lying on her back with her legs in
20 stirrups. The medical assistant
21 is standing next to me. There's a
22 sheet overlying the patient's
23 thighs and knees, and I'm sitting
24 down.

1 Initially, I will inspect
2 the external genitalia just with
3 my eyes and manually manipulate
4 the tissue; and then once the
5 external genitalia is inspected, I
6 will then ask permission to insert
7 a speculum or a finger into the
8 vagina to palpate, to feel the
9 tissue. So the vagina part of the
10 examination is both with a clear
11 plastic speculum as well as
12 manually or digitally.

13 During that time, I'll ask
14 the patient to cough, to strain,
15 meaning a Valsalva maneuver, what
16 we call a cough stress test.
17 While I'm looking with the clear
18 speculum, I'm looking for any kind
19 of vaginal foreign body. I'm
20 looking for the effects of
21 estrogen. I'm looking for pelvic
22 organ prolapse, looking to see if
23 there's any evidence of any
24 malignancy. I'm looking to see if

1 there's a cervix.

2 So that's what I'm primarily
3 performing during that portion of
4 the examination.

5 BY MR. McCONNELL:

6 Q. Okay.

7 Now, you noted, in that
8 paragraph, blue mesh. What, if anything,
9 did that indicate to you?

10 A. So mesh comes in a variety
11 of different colors, primarily clear mesh
12 or blue mesh. I like to distinguish
13 whether it was a clear mesh or blue mesh.

14 Occasionally, we don't know
15 what type of mesh was implanted and so we
16 could infer from the color of the mesh
17 what type of mesh it is.

18 So I could clearly see that
19 it was blue and that it was a mesh. I
20 could see that it was not a stitch. I
21 can see that there was a knit of fibers.
22 I didn't use a ruler to measure the 5 by
23 9 millimeter exposure, but I know that
24 the width of my thumb is 10 millimeters

1 in width, so sometimes that's a -- just
2 an easy way for me to use as a measuring
3 stick, so it was just slightly less than
4 the width of my thumb in its greatest
5 dimension, 9 millimeters; and then in the
6 opposite direction, it was half of that,
7 so 5 millimeters.

8 Q. And what does the blue mesh
9 infer to you?

10 A. The blue mesh, that it could
11 be a mesh from -- it could be an Ethicon
12 mesh. Some of the Ethicon meshes are
13 blue. Some of the original meshes, like
14 the original TVT, was clear, but TVT
15 Exact or TVT Secur are blue. Boston
16 Scientific has blue meshes, so it
17 possibly could be a Boston Scientific
18 device.

19 American Medical Systems and
20 Bard Urology, Coloplast, others, the
21 majority of the other meshes are clear
22 meshes. Some of the meshes may have more
23 than one color. Maybe they have a blue
24 and clear fiber weave, so I'm just

1 referring to simply the color of the
2 mesh.

3 Q. And you also made a finding
4 of no pain. How did you measure that?

5 A. I used the pain scale that's
6 commonly utilized called the visual
7 analogue pain scale. It's a widely
8 recognized score that physicians use when
9 assessing pain with patients.

10 I explained to the patient
11 ahead of time I'm going to assess your
12 pain. Zero would mean no pain. Ten
13 would mean the worst pain imaginable; and
14 then as I examine, I ask them to grade
15 the pain.

16 Q. And 0 over 10, does that
17 indicate that Mrs. Burnett exhibited no
18 pain or relayed to you no pain during any
19 of your exam?

20 A. That's correct.

21 Q. Can you turn to page 5 under
22 "Assessment and Opinions," please?

23 A. (Witness complies.)

24 Okay.

1 Q. Under "Vaginal Mesh
2 Exposure," you say that this would be
3 classified as a grade 2 complication.
4 What are the -- what are the range of
5 grade complications?

6 A. I believe the grading system
7 goes from 1 to maybe 8. The ones that I
8 commonly see in my practice would be 1,
9 2, 3, and 4.

10 So I'm familiar with the
11 grade 1 complication would be a patient
12 that had pain that was palpable over
13 their mesh, but there was no actual
14 exposure of the mesh.

15 A grade 2 would be that
16 there was an exposure of the mesh that
17 was less than 1 centimeter. Grade 3
18 would be more than 1 centimeter. Grade 4
19 is a mesh perforation into the lower
20 urinary tract, including the urethra and
21 the bladder.

22 Grade 5, 6, 7, 8, I'm less
23 familiar with as I don't really see those
24 in my practice.

1 Q. Are those -- is 5, 6, 7, 8
2 on the more severe end?

3 A. Yeah. So the grading system
4 goes from the least severe to the most
5 severe.

6 Q. The -- now, you say, this is
7 easily treated with partial transvaginal
8 mesh excision. What is the basis for
9 your opinion that this exposure is easily
10 treated?

11 A. That would be based on my
12 education, based on my experience in
13 practice treating similar patients. That
14 would be based on my review of the
15 medical literature.

16 Q. But what specifically can
17 you point to as part of your examination
18 of Mrs. Burnett that allows you to reach
19 that conclusion?

20 A. So if we go back to the
21 grading system, the lower the grade, the
22 easier to treat. If the mesh, say, for
23 instance, was a grade 4 into the lower
24 urinary tract and you removed it, you

1 would then have to repair the urinary
2 tract, in other words, you know, place
3 sutures in the urethra or the bladder to
4 fix a hole or opening.

5 Those are more time
6 consuming. They require a catheter
7 afterwards. There's a greater likelihood
8 of them developing stress urinary
9 incontinence afterwards.

10 Obviously, if it's eroding
11 or perforating into the GI tract, the
12 intestinal tract, that would be a much
13 harder one to fix.

14 Q. Okay.

15 A. So, you know, a vaginal wall
16 mesh exposure tends to be the simplest of
17 all the complications to treat.

18 Q. And have you treated grade 2
19 complications in the past?

20 A. I have.

21 Q. And have they all been
22 easily treated?

23 A. The overwhelming majority of
24 them.

1 Q. What are some examples of
2 grade 2 complications that aren't easily
3 treated? What happened?

4 A. That would be a patient that
5 had a recurrence of the exposure. That
6 would be a patient that, you know, had
7 injury to the lower urinary tract during
8 the removal or had bleeding that
9 occurred. Those things are more likely
10 to occur when removing larger pieces of
11 mesh or attempts at, you know, total or
12 complete mesh removal.

13 So the potential
14 complications depend a lot on how the --
15 how the surgery's done.

16 Q. Now, did Mrs. Burnett have a
17 recurrence of exposure during any of her
18 treatment?

19 A. I believe she initially had
20 an in-office mesh excision with Dr. Shirk
21 in 2008, so this would be considered a
22 recurrent mesh exposure.

23 Q. And those fall into a
24 category of potentially not so easily

1 treated, correct, or a complication?

2 A. That's not correct.

3 Q. Okay.

4 Well, I think I asked you
5 previously what would be potential
6 complications and you said a recurrence
7 of exposure; correct?

8 MR. SNELL: Object;
9 misstates.

10 Go ahead.

11 THE WITNESS: What you asked
12 me was, can you give me some
13 examples of which ones would be,
14 you know, harder to treat, that
15 would not be easy. And that's a
16 big category. Each one of those
17 is different.

18 Most physicians have moved
19 away from in-office mesh excision
20 or what's known as trimming
21 because that has been shown to be
22 ineffective.

23 So it depends on how the
24 initial patient was managed. I

1 know at least in my practice, the
2 overwhelming majority of the
3 patients have one excision and
4 don't require subsequent
5 excisions.

6 So this patient, if I
7 managed her, I could do this in a
8 one-hour outpatient procedure and
9 I would expect that there would be
10 less than a 5-percent chance of
11 her having a subsequent exposure.

12 BY MR. McCONNELL:

13 Q. But, in fact, she has had a
14 subsequent exposure already in this case;
15 correct?

16 A. Correct, or possibly
17 persistence. I don't know if the problem
18 was ever, you know, managed in 2008.

19 Q. And you also later on in
20 that paragraph decide that she may also
21 choose to live with chronic mesh
22 exposure; correct?

23 A. Correct.

24 Q. What are the risks of living

1 with chronic mesh exposure?

2 A. The main risk is, if there's
3 symptoms that are attributable to the
4 exposure, that they would continue.

5 Q. And what are those symptoms
6 -- in Mrs. Burnett's case, what are those
7 symptoms?

8 A. In Mrs. Burnett's case, she
9 doesn't have any symptoms. There's no
10 symptoms of the mesh exposure.

11 Q. What if she were to become
12 sexually active?

13 MR. SNELL: Object; form,
14 hypothetical.

15 Go ahead.

16 THE WITNESS: If she would
17 become sexually active, there's a
18 possibility that either her or her
19 partner would experience
20 discomfort during sexual
21 intercourse.

22 BY MR. McCONNELL:

23 Q. Okay.

24 In paragraph 2, "Recurrent

1 Mixed Urinary Incontinence," do you see
2 that?

3 A. I do.

4 Q. About the third sentence in,
5 third or fourth sentence in, you say,
6 "Her SUI has been present since 2007, one
7 year before her TVT Secur procedure."

8 Now, is that a typo, Doctor?

9 A. I don't believe so. I
10 probably could have stated it a little
11 more clearly, but what I'm saying there
12 is that her SUI began a year before she
13 elected to have surgery for it.

14 Q. And I may be reading it
15 wrong, but didn't -- wasn't her surgery
16 in 2007, in January?

17 A. In January of 2007, she had
18 her surgery, so -- so, yeah, it should be
19 her SUI has been present since 2006, so
20 you were reading it correctly. I should
21 have said her SUI's been present since
22 2006.

23 Q. Okay.

24 You can point -- so that's a

1 -- that is a typo.

2 A. That would be a typo.

3 Q. Okay.

4 And you can point to
5 something in her record that indicates
6 her SUI began in 2006?

7 A. I would have to go back and
8 look at Dr. Shirk's notes, but I believe
9 he had been seeing her and Dr. Ann
10 Metzger had been seeing her prior to
11 January of 2007, so there would have been
12 an evaluation period leading up to the
13 surgery.

14 Q. But under any circumstance,
15 we both agree her surgery for the mesh
16 implant was in January of 2007; correct?

17 A. I'm going through the
18 medical records just to confirm the
19 surgery date, but I believe that that was
20 the date when I -- I reviewed the records
21 last.

22 So I'm looking at an
23 operative report here. This is in my
24 binder under the first tab, TVT Secur,

1 Gerald Shirk, January 26, 2007. So,
2 yeah, that's the date of the surgery,
3 January 26, 2007.

4 Q. So with that in mind, how
5 would you amend that statement, if at
6 all?

7 A. The simplest way to amend it
8 was that she had incontinence that
9 existed sometime before 2007.

10 Q. Now, later on in that
11 paragraph -- or the bottom of that
12 paragraph -- excuse me -- you say:
13 Surgical therapy may include
14 transurethral bulking agent, mid-urethral
15 sling, or pubovaginal sling.

16 Correct?

17 A. Correct.

18 Q. Now, are you recommending
19 Mrs. Burnett undergo additional surgery
20 after having spoken to her for an hour
21 about her concerns about future surgery?

22 MR. SNELL: Object; form.

23 THE WITNESS: No, I didn't
24 make recommendations to her. What

1 I recommended was that she have
2 her urodynamics repeated. I don't
3 believe that that's been done
4 since in the preoperative
5 evaluation before her 2007
6 surgery.

7 So what I'm recommending is
8 that when you have a mixed
9 picture, meaning some complaints
10 of stress incontinence and some
11 complaints of urgency
12 incontinence, in a patient that's
13 had prior antiincontinence
14 surgery, what the AUA guidelines
15 would recommend is that this
16 patient undergo a urodynamic
17 evaluation to assess the type of
18 incontinence in order to
19 appropriately direct future
20 therapy.

21 BY MR. McCONNELL:

22 Q. But you do list as a future
23 treatment option potentially surgical
24 therapy, including mesh -- mesh slings.

1 A. Yeah, I listed transurethral
2 bulking agents, mid-urethral sling which
3 is synonymous with mesh slings, and
4 pubovaginal sling.

5 Q. Okay. And you do list that
6 as a future option, even though you are
7 aware of Mrs. Burnett's concerns about
8 the mesh and future surgeries; correct?

9 A. These are future options
10 that exist for patients with mixed
11 urinary incontinence, including Mrs.
12 Burnett. It would require informed
13 discussion, reviewing the options with
14 her. You'd have to look at how her
15 existing mesh exposure was managed. All
16 of those things would have to come into
17 consideration.

18 Q. But if she were your
19 patient, knowing her feelings, would you
20 still recommend future mesh surgery for
21 this patient?

22 MR. SNELL: Object; form.

23 THE WITNESS: It would

24 depend on how she would elect to

1 have her existing exposure
2 managed. That's the first
3 decision point.

4 So I can't say what future
5 decisions I would make until --
6 the first issue listed in the
7 assessment/opinions number 1 would
8 need to be addressed before you
9 can make recommendations on number
10 2.

11 BY MR. McCONNELL:

12 Q. In paragraph 3, you say in
13 the third or fourth sentence down, middle
14 of the paragraph: Her UTIs are not
15 caused by the TVT Secur mesh or vaginal
16 mesh exposure.

17 Do you see that?

18 A. I do.

19 Q. And can you give me the
20 basis for that statement?

21 A. The basis for that statement
22 is, I don't see anything in the medical
23 record to support the TVT mesh being the
24 cause of her urinary tract infections.

1 Q. And what led you -- what
2 specifically leads you to that
3 conclusion? You didn't see anything in
4 the medical records. What do you mean by
5 that?

6 A. I didn't see any information
7 on culture of the mesh or culture of the
8 urine that would implicate that the mesh
9 was the cause.

10 So, for instance, if the
11 urinary tract infections were always E.
12 Coli and someone had cultured the mesh
13 and that was E. Coli, well then, that
14 would suggest that possibly the mesh is a
15 cause.

16 If the mesh was perforating
17 into the lower urinary tract, that would
18 be more likely a cause. That's not
19 what's occurring in this case.

20 So those opinions are based
21 on the type of IUGA complication. So
22 this is a grade 2, so for grade 1, 2, and
23 3, I think it's much -- it's unlikely
24 that that would be the cause of the UTI.

1 If it's perforating into the
2 lower urinary tract, then that would be
3 more suggestive that that's the cause of
4 the UTI.

5 Other considerations is, if
6 the mesh was causing urethral obstruction
7 and bladder incomplete emptying and a
8 need for clean intermittent
9 catheterization, then that story would be
10 more suggestive as being a cause. That's
11 not occurring in this case; and I believe
12 when she saw Dr. Blaivas, he's ruled out
13 urethral obstruction as being a cause.

14 So people that I see with
15 recurrent urinary tract infections due to
16 prior antiincontinence surgery, it's
17 usually someone that's using a catheter
18 or someone with a perforation into the
19 lower urinary tract, and she doesn't have
20 either of those.

21 Q. Okay.

22 Can you turn to your
23 opinions regarding Mary Burnett? It's a
24 separate document.

1 A. (Witness complies.) Okay.

2 Q. On number 12 -- these are
3 all numbered, the paragraphs -- paragraph
4 number 12, you state that mesh exposure
5 at three months' postop is most likely
6 due a technical error and not a product
7 defect.

8 Do you see that?

9 A. I do.

10 Q. And what do you mean by a
11 technical error in that statement?

12 A. Technical error would imply
13 that there's wound failure, so her wound
14 failed or what we call healing
15 abnormalities.

16 But what I see ordinarily in
17 my surgical practice, regardless of the
18 location of the incision, when the
19 incision breaks down and the underlying
20 tissue or foreign body becomes exposed,
21 then that's usually related to a stitch
22 breaking or not enough stitches being
23 placed or tension on the incision. All
24 of these things would fall under the

1 broad category of wound failure or
2 technical failures.

3 Q. Did you see any of that in
4 Mrs. Burnett's case?

5 A. I believe when Dr. Gerald
6 Shirk had performed the postop
7 examination early on, he immediately
8 noted a mesh exposure, so, yes, I think
9 he saw that the wound had separated and
10 the mesh was exposed.

11 Q. And the mesh exposure was
12 caused by the mesh implant; correct?

13 MR. SNELL: Object; form.

14 THE WITNESS: No, that's not
15 correct.

16 BY MR. McCONNELL:

17 Q. Well, if there had been no
18 mesh implant, would there be a mesh
19 exposure?

20 A. The word mesh exposure,
21 yeah, you have to have mesh to have an
22 exposure. But there's many causes of
23 mesh exposure, not just the mesh so --

24 Q. Right. But to start at the

1 beginning, if there's no mesh, there's
2 not going to be any mesh exposure. You'd
3 agree with me on that; correct?

4 A. Correct.

5 Q. Now, did you agree with Dr.
6 Shirk that Mrs. Burnett was an
7 appropriate candidate for a mesh implant?

8 A. There are a few things in
9 the medical record that aren't clear
10 preoperatively, but at least from what
11 was available to me or what was performed
12 by Dr. Shirk, it did seem like she was a
13 reasonable candidate.

14 Q. And do you agree that Dr.
15 Shirk followed proper surgical procedure
16 in implanting the mesh into Mrs. Burnett?

17 A. Let me flip to his operative
18 report here.

19 Q. Okay.

20 A. I don't recall reading
21 anything unusual in the operative report.
22 It's a one-paragraph report.

23 He made a 1 1/2 inch
24 incision into the vaginal mucosa. He

1 created a dissection plane 2 centimeters
2 deep.

3 There's not a lot of detail
4 on how he placed the TVT Secur. It just
5 says the Secur was placed in the U
6 position.

7 I don't see anything that's
8 standing out at me, but without having
9 been there, there's just not a whole lot
10 of detail in this report.

11 Q. So you have no reason to
12 opine that Dr. Shirk did not follow
13 proper surgical procedure in this
14 implant; is that correct?

15 A. That's correct.

16 Q. Number 13, paragraph 13, Dr.
17 Flynn --

18 A. Yes.

19 Q. -- now, do you recall -- you
20 mentioned Dr. Metzger feeling a sharp
21 edge. And you reviewed her deposition;
22 correct?

23 A. I did.

24 Q. Do you recall her reaction

1 to how -- to when she felt the mesh?

2 MR. SNELL: Object; form.

3 THE WITNESS: Recall her
4 reaction? I believe that, you
5 know, she made Mrs. Burnett aware
6 of what she felt. I believe that
7 she had said in her deposition
8 that it cut her glove, is a
9 comment that I read in one of the
10 depositions, I believe.

11 BY MR. McCONNELL:

12 Q. And that she found the
13 sharpness of the mesh alarming? Do you
14 recall that?

15 A. I do.

16 Q. Does any of that testimony
17 of Mrs. Burnett's treating physician
18 factor into your opinion as to -- or any
19 of your opinions in this case?

20 A. Well, certainly I reviewed
21 Dr. Metzger's notes in detail and her
22 deposition and her interactions with Mrs.
23 Burnett, so, yes, that affects my
24 opinions. Dr. Metzger has been seeing

1 this patient for a number of years.

2 Q. And in what way does it
3 affect your opinion?

4 A. It affected my opinion to
5 the point that I included this in my
6 report. You know, paragraph number 13
7 describes that finding that she made, so
8 it was significant enough that I elected
9 to put it in my report.

10 Q. Did it affect your opinion
11 in this case in any other way other than
12 what you've described in paragraph 13?

13 A. I struggled a little bit
14 with her description of the location.
15 Maybe she misstated or corrected this in
16 her deposition, but at least in her
17 medical record, she said 9 o'clock in the
18 vaginal vault.

19 The vaginal vault is what we
20 would consider the apex of the vagina
21 where the cervix was. That's some 13
22 centimeters from the vaginal introitus.

23 So, typically, a mesh at the
24 mid-urethra would be no more than 2

1 centimeters from the urethral meatus, so
2 I was especially surprised by the
3 location when she said that she felt
4 something sharp at the vaginal vault.
5 That would lead me to believe that maybe
6 she was feeling the vaginal cuff scar or
7 that she was feeling something else.

8 She said it felt like mesh,
9 but she didn't definitively say it was
10 mesh. She didn't call it a blue mesh.
11 She didn't comment on the color of the
12 mesh. She didn't mention if she can
13 visualize it with a speculum.

14 So I -- that's what was
15 surprising to me, is just the location.

16 Q. But you don't have any doubt
17 that what she felt was the mesh; correct?

18 MR. SNELL: Object;
19 misstates.

20 THE WITNESS: That's
21 incorrect. I do have some doubts,
22 because I believe she was feeling
23 the vaginal cuff; and unless the
24 mesh was placed at the vaginal

1 cuff, which would have to have
2 been a surgical error by Dr.
3 Shirk, the mesh can't move from
4 the mid-urethra to the vaginal
5 cuff.

6 So either Dr. Metzger meant
7 to say the anterior vaginal wall
8 when she said vaginal vault or Dr.
9 Shirk placed the mesh at the
10 vaginal apex, which I know he
11 didn't because when I examined
12 Mrs. Burnett, I can see the mesh 1
13 centimeter from the urethra. I
14 commented on that in my IME.

15 So I know if you're 1
16 centimeter from the urethra, you
17 can't be at the vaginal vault at
18 the same time.

19 BY MR. McCONNELL:

20 Q. So with that explanation,
21 what do you think it is most likely about
22 what Dr. Metzger felt?

23 MR. SNELL: Object; form,
24 asked and answered.

1 THE WITNESS: I'm not
2 certain. I know that she's
3 feeling some scar tissue -- that
4 could be scar tissue from her
5 hysterectomy -- or she didn't
6 document in the record correctly
7 where she was feeling the mesh or
8 -- I don't remember what she said
9 in her deposition about that
10 comment. I'd have to go back and
11 reread that.

12 BY MR. McCONNELL:

13 Q. Well, scar tissue wouldn't
14 almost cut her -- or wouldn't cut her
15 glove, would it?

16 A. Could scar tissue cut a
17 glove? No, I don't believe so.

18 Q. Could mesh cut a glove?

19 A. I think that's extremely
20 unlikely. It's never happened to me.

21 Q. Of the two, what would be
22 more likely to cut a glove, scar tissue
23 or mesh?

24 A. I think they would be

1 equally -- both of them would be equally
2 unlikely.

3 Q. But of the two, which would
4 be more likely to cut a glove?

5 MR. SNELL: Object; asked
6 and answered.

7 THE WITNESS: I think it's a
8 tie. I think -- either scenario
9 has never happened to me in
10 thousands of pelvic exams. And
11 I've examined a number of women
12 with mesh exposures. I've
13 surgically removed exposed mesh.
14 I've never had a glove cut from
15 mesh.

16 BY MR. McCONNELL:

17 Q. But Dr. Metzger did;
18 correct?

19 MR. SNELL: Object; form,
20 foundation now.

21 MR. McCONNELL: At least
22 according to her testimony.

23 MR. SNELL: Same objections.

24 THE WITNESS: I'm not going

1 to agree to that. She stated that
2 she cut her glove, but I'm not
3 certain she was feeling mesh.

4 BY MR. McCONNELL:

5 Q. But you don't know what she
6 was feeling; is that what you're saying?

7 A. If it was at the vaginal
8 apex, she was not feeling the mesh. So,
9 you know, I'd have to hear her answer to
10 that question to know what she was
11 feeling, but at least according to the
12 medical record, it states that she was
13 feeling at the vaginal vault.

14 That's not the location of
15 the mesh. Based on my exam, based on Dr.
16 Blaivas' exam, based on Dr. Shirk's, Dr.
17 Mindrup's, the mesh has never been at the
18 vaginal vault.

19 Q. But you know according to
20 her testimony which -- you said that she
21 felt -- she was describing the mesh and
22 she felt it was alarming that the mesh
23 cut her glove; correct?

24 MR. SNELL: Object; lacks

1 foundation, form.

2 THE WITNESS: That's what
3 she stated in the deposition, but
4 I don't believe she's ever
5 reconciled that with the statement
6 of being at the vaginal vault.

7 BY MR. McCONNELL:

8 Q. In numbered paragraph 32,
9 you state in the middle of that paragraph
10 that Dr. Blaivas hypothesizes that there
11 could be mesh perforation into the
12 bladder or urethra; correct?

13 A. Correct.

14 Q. Did Dr. Blaivas in his
15 report or deposition say he was
16 hypothesizing?

17 A. I don't believe he used the
18 word "hypothesis," but he implied that
19 the mesh could be inside the lower
20 urinary tract, and there's no foundation
21 for that. That's speculation.

22 Q. Well, according to you, why
23 does he -- in his opinion, why does he
24 believe there could be mesh perforation

1 into the bladder or urethra?

2 MR. SNELL: Object; form.

3 THE WITNESS: I don't
4 believe that was his opinion. I
5 believe he was listing a
6 differential diagnosis of all the
7 things that could possibly be
8 occurring, but I don't believe
9 that he was implying that.

10 What we do know is that her
11 most recent cystoscopy, less than
12 two years ago, performed by Dr.
13 Mindrup, her urologist, had showed
14 that there was no perforation into
15 the lower urinary tract.

16 BY MR. McCONNELL:

17 Q. In paragraph 34, you say you
18 reviewed Dr. Rosenzweig's report and you
19 disagree with his opinions that TVT Secur
20 and laser cut mesh are defective
21 products. And you say: Laser cut mesh
22 mid-urethral slings are commonly used
23 today by myself and most pelvic surgeons.

24 Did I read that correctly?

1 A. You did.

2 Q. Therefore, are you saying
3 that a product can't be defective because
4 it's commonly used?

5 A. There's two statements
6 there. It says, laser cut mid-urethral
7 slings are used commonly today by myself
8 and most pelvic surgeons. So I think
9 that statement is very straightforward.
10 And that's true. If you look at the AUGS
11 statement that I brought, if you look at
12 surveys of their members, if you ask me
13 questions about what I use in my
14 practice, most pelvic floor surgeons
15 continue to perform mid-urethral slings.
16 Most mid-urethral slings 2016 are laser
17 cut.

18 The first statement reflects
19 to -- just that laser cut mesh is
20 defective, and I don't believe laser cut
21 mesh is defective.

22 Q. But the second statement
23 comes after the first statement and my
24 question is, is it your opinion that a

1 product can't be defective because it's
2 being commonly used? Is that what you
3 meant to say there?

4 MR. SNELL: Object; form.
5 Go ahead.

6 THE WITNESS: That's not
7 what I meant to say and that's not
8 what I said. It's not a
9 compounded sentence. There are
10 two independent statements. So --

11 BY MR. McCONNELL:

12 Q. One following the next in
13 the same paragraph.

14 A. Yeah. If a mesh is used
15 commonly, I would say it's very unlikely
16 to be defective if it's been on the
17 market for many years and used by 95
18 percent of AUGS members who have, you
19 know, tens of thousands of years of
20 combined experience using these products,
21 performing these surgeries.

22 So, you know, I would say
23 that it's a lot less likely compared to,
24 say, a new product that we have little or

1 no information on.

2 Q. Okay.

3 In paragraph 35, you discuss
4 -- you attribute the exposure to
5 estrogen/hormonal deficiency; correct?

6 A. Correct.

7 Q. Doctor, do most women as
8 they age experience vaginal atrophy?

9 A. Most postmenopausal women
10 experience vaginal atrophy.

11 Q. And that's a natural
12 occurrence?

13 A. That's a natural occurrence
14 with aging.

15 Q. And the mesh implant is a
16 permanent implant?

17 A. It's meant to be permanent,
18 yes.

19 Q. Would you therefore expect
20 that mesh exposure in most women with
21 this type of permanent implant as they
22 age?

23 MR. SNELL: Object; form.

24 THE WITNESS: Not

1 necessarily, no.

2 BY MR. McCONNELL:

3 Q. And why not, presuming --
4 with the understanding that vaginal
5 atrophy occurs in most women naturally
6 and that the mesh is a permanent implant?

7 A. Well, if you look at the
8 exposure rate in the medical literature
9 for the TVT Secur device, most would
10 agree that it's less than 5 percent,
11 other reports that it's even lower than
12 that, 1.5 percent.

13 And so if you just look at
14 the body of literature that's out there,
15 most women are not experiencing mesh
16 exposures, and a large percentage of the
17 women that have mesh implanted are
18 postmenopausal.

19 Q. Are you saying to a
20 reasonable degree of medical certainty
21 that mesh exposure, in Mrs. Burnett now,
22 is not caused by a defect in the TVT
23 Secur mesh?

24 A. That's correct.

1 Q. On the next page, paragraph
2 37, you say Mrs. Burnett -- Mrs. Burnett
3 has no symptoms directly attributed to
4 the TVT Secur mesh exposure.

5 But what about her anxiety
6 or stress that she expressed to you?
7 Would you consider that to be a symptom
8 of the mesh exposure?

9 A. I don't recall her voicing a
10 significant amount of anxiety to me
11 during the IME. I don't believe she's on
12 any antianxiety pills or seeking
13 treatment for anxiety, so I'm not clear
14 on the anxiety that you're talking about.

15 Q. Well, having interviewed
16 her, did she have any concern whatsoever
17 about having mesh exposure in her body?
18 Was it your recollection she stated
19 anything of that nature?

20 A. She had concern. That's
21 very different than anxiety.

22 Q. What was her concern?

23 A. Her concern would be what
24 the future holds for her and what

1 treatment options are available to her.

2 Q. Would you consider that
3 concern to be a symptom attributed to her
4 TVT Secur mesh exposure?

5 A. No, I don't. Symptoms -- I
6 describe symptoms as physical symptoms,
7 so vaginal discharge, vaginal bleeding,
8 burning, dyspareunia, those are what
9 would be considered local symptoms,
10 symptoms located where the complaint is.

11 And then there's what we
12 refer to as systemic symptoms, that is,
13 the system's response to the exposure,
14 fever, chills, nausea, vomiting. Those
15 things are things that we describe as
16 systemic symptoms.

17 I don't think people -- a
18 concern is a reaction. That's not a
19 symptom, so that's the way the patient
20 processes the information at hand.

21 Q. Well, then you'd agree that
22 Mrs. Burnett has a reaction that can be
23 directly attributed to the TVT Secur mesh
24 exposure; correct?

1 A. I believe that she has
2 concern about it. She's been through a
3 number of IMEs. She's seen a number of
4 experts. She's met with her primary care
5 doctor about it.

6 But I don't believe she's
7 voiced any anxiety to Dr. Metzger, her
8 long-term physician, or to Dr. Mindrup,
9 her urologist. She's never been
10 insistent that she requires surgery.

11 To me, she seems to be
12 behaving appropriately based on the local
13 complaints that she has.

14 Q. In paragraph 38A, you say:
15 Mesh exposure has been estimated to occur
16 in only 2.0 to 4.7 percent of patients
17 receiving the TVT Secur. And you
18 reference an article on that.

19 In those situations or in
20 those circumstances, what is the reason
21 for the mesh exposure?

22 A. I don't believe the authors
23 in a meta-analysis or systematic review
24 give a reason. They may mention in the

1 discussion some of the potential causes,
2 but each one of these is different, so I
3 wouldn't say there's one reason why
4 there's a mesh exposure. There's
5 multiple reasons why mesh can be exposed.

6 Q. Now, is Ms. Burnett
7 complaining about dyspareunia?

8 A. She's not.

9 Q. But that's -- you cite that
10 or you list dyspareunia in 38B; correct?

11 A. I do.

12 Q. And why do you do that?

13 A. Because she claims that she
14 had the following injuries: vaginal mesh
15 exposure, stress urinary incontinence,
16 urinary tract infections.

17 And I think that oftentimes
18 plaintiffs will complain of dyspareunia
19 as a result of their mesh exposure, so
20 although she hasn't complained about
21 that, it doesn't mean that she won't in
22 the future.

23 Q. Did you list any other
24 problems that she may encounter in the

1 future in your report?

2 A. De novo overactive bladder
3 is listed, vaginal scarring, I listed.
4 So there was a few others beyond the
5 three that were on her complaint form.

6 Q. In paragraph 39 on the next
7 page, you state: I disagree with Dr.
8 Blaivas on the cause of plaintiff's
9 complaints as the published medical
10 literature on the use of polypropylene as
11 a whole refutes his opinion.

12 And can you give me a basis
13 for that statement? What literature are
14 you referring to?

15 A. I'm referring to the Schimpf
16 meta-analyses. There's multiple
17 meta-analyses that he has performed. The
18 TVT Secur registry, the professional
19 statements from the various medical
20 societies, the Cochran reviews.

21 There's well over a hundred
22 RCTs based on TVT mesh that really do not
23 support Dr. Blaivas' opinions that the
24 mesh is defective.

1 Q. And you further on in that
2 paragraph list, there's no indication of
3 degradation, roping, curling, particle
4 loss, fraying, contraction, or any other
5 defect alleged by Dr. Blaivas.

6 Do you see that?

7 A. I do.

8 Q. And you say there was no
9 evidence in your exam of such things?

10 A. Correct.

11 Q. And what, if anything, in
12 addition to how you -- what you've
13 already described as your exam did you do
14 to rule out or to not find any of those
15 such things?

16 A. Well, I reviewed Dr.
17 Blaivas' IME and I reviewed Dr. Ann
18 Metzger's medical records, Dr. Shirk's
19 medical records, Dr. Mindrup's medical
20 records. So in addition to my own IME, I
21 looked at plaintiff expert reports and I
22 looked at treating physician reports, and
23 none of the physicians mention
24 degradation, roping, curling, or particle

1 loss, or fraying, or contracture in their
2 physical exams or in their operative
3 reports.

4 There's no pathology report
5 that I'm aware of in this case. There
6 was office trimming that was performed,
7 so there was no actual mesh explantation.
8 So that's what that's based on. There's
9 no pathology report. There's no picture.
10 There's nothing documenting any of these
11 alleged product defects.

12 Q. Now, you're not an expert on
13 warnings; correct?

14 MR. SNELL: Object; form.

15 MR. McCONNELL: I'm sorry?

16 THE WITNESS: I have
17 expertise in looking at warnings
18 in IFUs, patient brochures.

19 BY MR. McCONNELL:

20 Q. I'm sorry, Doctor. You have
21 expertise in -- can you repeat that
22 answer? I --

23 A. Yeah, I have expertise in
24 reviewing warnings, such as the FDA

1 warning, which would be more properly
2 stated as a public health notification
3 that occurred in 2008. I wrote a
4 response; that the AUA asked me to write
5 a response on their behalf in 2008 in
6 their update series. So I believe that I
7 have expertise in warnings.

8 I've looked at what the FDA
9 documents had shown.

10 Q. Well, you haven't done any
11 academic study or you haven't written any
12 literature on the history of warnings on
13 medical products or on any type of device
14 or product, have you?

15 MR. SNELL: Object; form.

16 THE WITNESS: In my 2008 --
17 2010 -- excuse me -- AUA update,
18 there's a number of paragraphs on
19 how products are cleared by the
20 FDA, what the 510(k) approval
21 process is. I have -- I'm very
22 familiar with that process.

23 I didn't have a separate
24 publication, but there's a whole

1 section on reviewing how the FDA
2 clears products, and I have been
3 very familiar with documents that
4 the FDA uses as guidelines for
5 clearing products.

6 BY MR. McCONNELL:

7 Q. And how did you come about
8 that? Did you do any -- did you take any
9 courses? Did you do any academic
10 studying? Did you do any literature
11 research or how did you come up with
12 those paragraphs that you reference in
13 the year 2010 response?

14 A. Well, Ryan Terleki, who was
15 my fellow at the time, him and I wrote
16 the article together. We had
17 communication with the FDA about the
18 warning and they immediately corrected us
19 and said they didn't put out a warning,
20 it was a public health notification.

21 And then through our
22 literature review on PubMed, we came up
23 with articles that we cited in the
24 update, and so we looked at those

1 articles on how medical devices are
2 cleared.

3 I have prepared lectures on
4 this topic, so I've been reviewing this
5 for a number of years. I've shared the
6 FDA public health notifications with my
7 patients. I've looked at position
8 statements from IUGA and AUGS,
9 round-table discussions of experts in
10 regards to the implications of the FDA
11 public health notification.

12 So I feel I've done my
13 research on this topic.

14 Q. And those are your criteria
15 for calling yourself an expert on
16 warnings. Am I right?

17 A. That's correct.

18 Q. At the end of -- on page 6,
19 towards the end of paragraph 42, you say:
20 The IFU did not in my opinion need to
21 warn about the management of
22 complications or, quote, the difficulty
23 and risks involved in removing the
24 device, because those are also well-known

1 to pelvic floor surgeons.

2 Do you see that?

3 A. I do.

4 Q. Is it your opinion, Doctor,
5 that there is no need to warn when people
6 are generally aware of a risk?

7 A. It's my opinion and it's
8 also the opinion of the FDA. The FDA has
9 guidelines for manufacturers looking at
10 prescription devices that they
11 specifically itemize when you need to
12 warn.

13 And if something is
14 considered public knowledge that a
15 reasonable physician would know and be
16 aware of, that you don't need to warn of
17 that because it's not unique to the
18 product.

19 MR. McCONNELL: Give me one
20 minute.

21 (Pause.)

22 MR. McCONNELL: Doctor, I
23 think those are all the questions
24 I have. Thank you very much.

1 THE WITNESS: Thank you.

2 - - -

3 EXAMINATION

4 - - -

5 BY MR. SNELL:

6 Q. Doctor, I just have a few
7 follow-up questions, and I'm going to
8 start from the back and work -- work
9 backwards actually.

10 You just mentioned
11 regulations that you're aware of
12 concerning no need to warn when a
13 reasonable physician would have the
14 awareness or knowledge of something that
15 was common across different surgeries or
16 devices; is that correct?

17 A. That's correct.

18 Q. And part of what you're
19 relying on, is that the CFR, the Code of
20 Federal Regulations, on labeling, 801.109
21 - Prescription Devices, where it
22 discusses information that may be omitted
23 from the labeling if the information is
24 commonly known to practitioners licensed

1 by law to use the device?

2 MR. McCONNELL: I'll object.

3 THE WITNESS: That's

4 correct.

5 BY MR. SNELL:

6 Q. And the practitioners
7 licensed to use this device, TVT Secur,
8 would that be talking about pelvic floor
9 surgeons like yourself?

10 A. Yes.

11 Q. You were asked questions --
12 and let's turn, if you would, to your
13 report, page 13 -- I'm sorry -- your
14 report at page 1, paragraph 13.

15 A. (Witness complies.)

16 Q. Do you recollect discussing
17 with plaintiff's counsel the issue about
18 Dr. Metzger who claimed she felt a sharp
19 edge in the vaginal vault which felt like
20 mesh?

21 A. I do recall.

22 Q. Now, I have Dr. Metzger's
23 testimony here. And beginning at page
24 22, line 23, she's asked about that

1 bimanual examination.

2 Do you see that?

3 A. I do.

4 Q. And did she say that she
5 found that sharp edge down at the
6 mid-urethra portion of the vagina or at
7 the vaginal vault?

8 A. It says: A very, very sharp
9 edge at the 9 o'clock in the vaginal
10 vault that felt like mesh, and I remember
11 I almost cut my finger and I took my
12 glove off to look.

13 Q. And then she was asked again
14 about whether this feeling was at the
15 vaginal vault or somewhere else. And
16 what did she testify as to whether it was
17 at 9 o'clock at the vaginal vault, page
18 23, line 6?

19 A. It says: You said it was at
20 the 9 o'clock in the vaginal vault.
21 Answer: That's what it felt like, yes.

22 So she's agreeing to the
23 question that it was at 9 o'clock and at
24 the vaginal vault.

1 Q. And then they asked her --
2 at page 23, lines 17 down through 20,
3 does she describe essentially how large
4 of an area this was?

5 A. She did. She said: I think
6 it felt like almost 2 centimeters.

7 Q. And on that topic of whether
8 she thought it was mesh, she was asked:
9 Have you felt mesh exposure before?

10 And line 25, she says: I
11 don't recall actually ever feeling mesh
12 like -- or, you know, there could be
13 maybe one person, but it was just kind of
14 intertwined within the vaginal vault, but
15 never something this sharp.

16 Do you see that?

17 A. I do.

18 Q. Page 25, lines 14 down --

19 MR. McCONNELL: Counsel, for
20 completion, can you just read up
21 the page to line 11 on page 25?

22 MR. SNELL: No, I mean, you
23 can do that, counsel. I'm just
24 asking him about the vaginal

1 vault.

2 BY MR. SNELL:

3 Q. Page 25, beginning at line
4 14, she was asked the question and does
5 she state whether or not she was actually
6 cut that day?

7 A. She said: No, I mean -- I
8 mean, I just remember I was not cut that
9 day, but it was sharp, so I thought I
10 was.

11 Q. And then at page 61 -- this
12 was the examination by one side -- so so
13 far, where exactly was this feeling
14 located, at the area where the sling
15 would be or at the vaginal vault?

16 A. Are you referring to my exam
17 or Dr. Metzger's exam?

18 Q. Dr. Metzger's exam, as well
19 as her testimony, sworn testimony, about
20 where this feeling was based on her exam.

21 MR. McCONNELL: Objection.

22 THE WITNESS: So based on
23 her exam and her testimony, she
24 says that it was at the vaginal

1 vault.

2 BY MR. SNELL:

3 Q. At page 61, now she was
4 asked again about the conversation she
5 had with Mrs. Burnett about the findings
6 of the sharp edge in the vaginal vault.
7 Do you see that?

8 A. I do.

9 Q. And the answer was: Uh-huh.
10 Is that correct?

11 A. That's correct.

12 MR. McCONNELL: Objection.

13 BY MR. SNELL:

14 Q. So the evidence in this
15 case, Doctor, can you tell us whether Dr.
16 Metzger, based on her exam, her record,
17 and her testimony, indicates that she
18 found this area -- where it was within
19 the vagina?

20 A. Based on Dr. Metzger's exam
21 and testimony, it was at the vaginal
22 vault.

23 Q. And you testified that the
24 sling is very far distance away from the

1 vaginal vault; is that correct?

2 A. That's correct.

3 MR. McCONNELL: Objection.

4 THE WITNESS: Yes, that's
5 correct.

6 BY MR. SNELL:

7 Q. Based on your exam of the
8 plaintiff, where was the sling?

9 A. The sling was 1 centimeter
10 to the right of the urethral -- of the
11 urethra. I felt a 5 by 9 millimeter
12 exposure on the right side. That's on
13 the anterior vaginal wall, underneath the
14 urethra, the bladder.

15 It's certainly not the
16 vaginal vault.

17 Q. And do you have an opinion
18 as to whether whatever it was that Dr.
19 Metzger felt at the vaginal vault,
20 whether that was mesh from the TVT Secur?

21 A. I do.

22 Q. And what is that opinion?

23 A. That it was not TVT mesh.
24 That was just a vaginal cuff scar.

1 Q. And, anatomically, is it
2 even possible that -- based upon your IME
3 exam, that the TVT Secur mesh could have
4 been up in the vaginal vault at the time
5 Dr. Metzger reported finding this
6 sensation?

7 A. Yeah, it's not possible
8 based on my exam, based on Dr. Blaivas'
9 exam, Dr. Mindrup, and Dr. Shirk. None
10 of the other treaters or experts had ever
11 noted the mesh to be at the vaginal
12 vault.

13 Q. And because I believe
14 plaintiff's counsel represented that the
15 glove was actually cut, based upon Dr.
16 Metzger's sworn testimony, did she
17 actually have her finger or glove cut?

18 A. She mentioned that she was
19 concerned, so she took her glove off to
20 see if her finger was cut and, in fact,
21 it was not.

22 MR. McCONNELL: And I'm
23 going to object to plaintiff's
24 counsel's representation. I was

1 repeating what Dr. Flynn said for
2 the record.

3 BY MR. SNELL:

4 Q. Now, you mention that you've
5 done a general TVT Secur report?

6 A. I have.

7 Q. Do you incorporate that and
8 the bases and data set forth in that
9 report into your case-specific report in
10 this case?

11 MR. McCONNELL: I'm going to
12 object. This is a case-specific
13 deposition, not a general
14 deposition.

15 MR. SNELL: You can answer.

16 THE WITNESS: Yes, I
17 mentioned that when I went on the
18 record earlier in the deposition,
19 in terms of the number of hours I
20 worked on this case, I had
21 prepared a TVT Secur report.

22 I didn't include those hours
23 in preparing this report, but
24 certainly it affected my opinions

1 in this report, especially in
2 response to the complaints against
3 the device alleged by Dr.
4 Rosenzweig and Dr. Blaivas.

5 BY MR. SNELL:

6 Q. And at page 43 -- I'm sorry.
7 I keep getting those pages and numbers --
8 at page 6, paragraph 43, where you talk
9 about your opinions and the bases and
10 whatnot, do you not state: I hereby
11 incorporate in this report the opinions
12 set forth in my general report regarding
13 TVT Secur device?

14 A. I do.

15 MR. McCONNELL: Objection.

16 BY MR. SNELL:

17 Q. Have you already sat for a
18 general deposition on those opinions?

19 A. I have.

20 Q. Did you do professional
21 education on mesh products?

22 A. I have.

23 Q. And as part of --

24 MR. McCONNELL: Objection.

1 BY MR. SNELL:

2 Q. As part of that --

3 MR. McCONNELL: This is not
4 a general exam.

5 MR. SNELL: No, it's not.
6 I'm about to tie it to what you
7 asked him about.

8 MR. McCONNELL: Okay.

9 BY MR. SNELL:

10 Q. And when you did
11 professional education on those mesh
12 products, besides talking about the
13 devices or their surgical implantation,
14 did you also cover the IFU steps and the
15 material identified in the IFU?

16 A. Yes.

17 Q. And is that a --

18 MR. McCONNELL: Objection.

19 BY MR. SNELL:

20 Q. And plaintiff's counsel
21 asked you about your expertise on
22 warnings. Is that a further basis for
23 your expertise and experience with regard
24 to IFUs and warnings --

1 MR. McCONNELL: Objection.

2 BY MR. SNELL:

3 Q. -- for a device like TVT
4 Secur?

5 A. Yes, it is.

6 Q. Do you recall being asked
7 about the urinary tract infections that
8 Mrs. Burnett had?

9 A. I do.

10 Q. And you opine that you do
11 not believe that the TVT Secur caused the
12 urinary tract infections.

13 Let me ask you this
14 question: In paragraph 3, you noted that
15 plaintiff had been treated for at least
16 three urinary tract infections before her
17 TVT Secur implant.

18 A. That's correct.

19 Q. And then after TVT Secur,
20 paragraph 8, I only see one urinary tract
21 infection that was referenced.

22 A. Correct.

23 MR. McCONNELL: Objection.

24 BY MR. SNELL:

1 Q. And then you state at
2 paragraph 15, in 2008, she underwent the
3 laparoscopic Burch procedure; correct?

4 A. Correct.

5 Q. And after she underwent the
6 Burch, did she have urinary tract
7 infections?

8 A. She did. She had, I
9 believe, three urinary tract infections
10 in a short time period following the
11 Burch.

12 Q. And does that chronology of
13 urinary tract infections, the fact that
14 she had three before TVT Secur at least,
15 one while on TVT Secur, and at least
16 three after the laparoscopic Burch, is
17 that supportive or not supportive of your
18 opinion that TVT Secur did not cause her
19 urinary tract infections?

20 MR. McCONNELL: Objection.

21 THE WITNESS: That supports
22 my opinion that TVT Secur did not
23 cause her urinary tract
24 infections. The time course makes

1 no sense. She had three UTIs
2 before she ever had Secur. She
3 had one UTI immediately following
4 and then had three after her
5 Burch.

6 She eventually had to see
7 Dr. Mindrup for recurrent UTIs, a
8 urologist. Dr. Mindrup's opinion
9 was that the mesh is not causing
10 her UTIs. He stated that in one
11 of his office notes.

12 He put her on antibiotics
13 for six months and afterwards was
14 able to stop the antibiotics and
15 has not had an infection since
16 that time.

17 So I don't believe the TVT
18 Secur or the TVT Secur mesh
19 exposure is the cause of her
20 recurrent urinary tract
21 infections.

22 MR. SNELL: That's all I
23 have. Thank you.

24 MR. McCONNELL: I just have

1 a couple follow-ups.

2 - - -

3 EXAMINATION

4 - - -

5 BY MR. McCONNELL:

6 Q. Dr. Flynn, didn't Dr.
7 Metzger refer Mrs. Burnett back to Dr.
8 Shirk after her examination?

9 A. She did.

10 Q. And didn't Dr. Shirk at that
11 point perform the excision of mesh in his
12 office on Mrs. Burnett?

13 A. That's correct.

14 Q. And wouldn't common sense
15 indicate to you that what Dr. Metzger was
16 feeling was the mesh that Dr. Shirk
17 thereafter excised in his office?

18 MR. SNELL: Object; form.

19 THE WITNESS: No, I
20 disagree.

21 BY MR. McCONNELL:

22 Q. Why?

23 A. Again, the location of what
24 she described on her exam and her dep --

1 and in her deposition, it just doesn't
2 make any sense.

3 So -- Dr. Shirk is, you
4 know, more qualified to do examinations.
5 I think that he had concerns about a mesh
6 exposure and he excised the mesh
7 exposure. This was a decision that Dr.
8 Shirk made independent of Dr. Metzger.

9 Q. So your testimony under oath
10 this morning is that a treating physician
11 who felt alarmed at feeling something
12 sharp and thought she may have cut her
13 glove, who therefore then sent her back
14 to the implanting physician who
15 immediately performed an excision of mesh
16 in his office, that your opinion under
17 oath is that you don't believe that what
18 that treating physician felt and was
19 alarmed by was mesh; is that what you're
20 telling the jury?

21 A. That's what I'm telling the
22 jury, yes.

23 MR. McCONNELL: Okay.

24 Thanks very much.

1 THE WITNESS: All right.

2 Thank you.

3 (Witness excused.)

4 (Deposition concluded at
5 approximately 11:10 a.m.)

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2 CERTIFICATE
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5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, BRIAN J. FLYNN, M.D., have the
12 opportunity to read and sign the
13 deposition transcript.

14 _____
15 KIMBERLY A. CAHILL, a
16 Federally Approved Registered
17 Merit Reporter and Notary Public
18 Dated: July 23, 2016
19

20 (The foregoing certification
21 of this transcript does not apply to any
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23 unless under the direct control and/or
24 supervision of the certifying reporter.)

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2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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Brian J. Flynn, M.D.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 92, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

BRIAN J. FLYNN, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

Notary Public

Brian J. Flynn, M.D.

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